

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
)	Master File No. 01-12257-PBS
)	Subcategory Case No. 06-11337
)	
)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO:)	
<i>State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.</i>)	Magistrate Judge
)	Marianne B. Bowler
Case No: 1:03-cv-11226-PBS)	
)	

**PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED
MATERIAL FACTS AS TO DEFENDANTS DEY, L.P. AND DEY, INC.**

A. Medi-Cal Pharmacy Providers Submitted Claims for Dey Drugs Based on Dey's AWPs Reported to First DataBank which were Paid By Medi-Cal with Government Funds.

1. During the period from 1994 through 2004, pharmacies and other Medi-Cal providers routinely submitted pharmaceutical claims to Medi-Cal (through its fiscal intermediary, EDS) for reimbursement of the Dey drugs at issue in this action (the "Subject Drugs") that those providers had dispensed to program beneficiaries. (Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment as to Dey (hereinafter, "Paul"), Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

2. Medi-Cal paid those claims (through EDS) with Government funds. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

3. Pursuant to applicable statutory and regulatory requirements, the claims were adjudicated and paid *at the lesser of* the provider's usual and customary charge or at the Cost of the Drug Product plus a dispensing fee. By statute, the total payment was then reduced by an amount varying over time from \$.10 to \$.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

4. The Cost of the Drug Product was set at *the lowest of* the drug's Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost (FAC, a/k/a FUL), or the Maximum Allowable Ingredient Cost (MAIC).¹ (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWPs reported by First Data Bank ("FDB") less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

B. Dey Set AWPs for its Drugs and Reported those AWPs to the Pricing Compendia Without Regard to the Real Selling Prices.

6. Throughout the relevant time period, Dey set AWPs for its products. (Paul Ex. 2 (11/1/01 Robert Mozak Dep.), at 23:23- 24:1.)

7. During the relevant time period, Dey set AWPs for its generic drugs before they were first sold and generally did not subsequently change the initially-set AWPs. Dey's Responses to California's First Set of Requests for Admission, June 30, 2009:

Request No. 11: "Admit that Dey's AWPs for each of the Subject Drugs was not based on an average of any wholesale prices."

Dey's Response: "...Dey states that, during the relevant time period, Dey's practice has been to set AWPs for its generic drugs before they are first sold and not to subsequently change that AWP.

(Paul Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 11 at p. 13.)

8. When Dey was the first to market a generic product, Dey set the AWP at approximately 10 percent below the branded product. (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 731:11-732:9; Paul Ex. 5 (3/24/03 Charles A. Rice Dep.), at 604:16-21; Paul Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 11 at pp. 13-14.)

¹ There are no claims paid at MAIC at issue in this case.

9. When Dey launched a product and there was already a competitive generic product on the market, Dey set its AWP by reference to the competitor's AWP. (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 731:11-732:9.)

10. Dey knew that "competition forces prices down on [a] generic product." (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 739:7-16. Dey responded to such competition by consistently lowering the selling price of its products. (Paul Ex. 6 (4/30/02 Robert Mozak Dep.), at 272:9-20.)

11. Dey generally did not change its reported AWPs in response to changes in transaction prices for its products; its practice was to set a product's AWP at launch and to not change that AWP. (Paul Ex. 7 (Decl. of Russell Johnston in Support of Plaintiff's Ex Parte Application for a Temporary Restraining Order, *Dey v. First DataBank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 4, ¶16; Paul Ex. 8 (11/7/02 Charles A. Rice Dep.), at 427:3-4; *see also* Number 7 above.)

12. Dey's practice of dropping the price of a generic product while maintaining the originally-reported AWP served to increase the reimbursement spread of that product.

Dey's Responses to California's First Set of Requests for Admission, June 30, 2009,
Request No. 24

Admit that you never disclosed to Medicaid officials responsible for reimbursement for Your Subject Drugs the actual spreads on those products.

Dey's Response:

...."Second, if the spread for a particular generic Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower." ...

(Paul Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 24 at p. 32; Paul Ex. 9 (2/7/94 Robert Mozak letter), at DEY-BO-0189566-0189570 (Dey characterizes its pricing on a product as the "lowest net price, highest retailer spread versus AWP").)

13. Dey acknowledged that it did not lower its reported AWPs because, given the reimbursement system, customers would not buy Dey's products if it lowered the AWPs. (Paul Ex. 10 (5/15/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 133:6-9, 141:14-142:4.)

14. Dey was aware that it was necessary to report AWPs to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. Paul Ex. 11 (Compl. for Injunctive Relief, *Dey v. First Data Bank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 7:27-28; Paul Ex. 8 (11/7/02 Charles Rice Dep.), at 409:13-25.) The former head of Dey's Sales and Marketing, Robert Mozak, also knew that Medicaid authorities calculated reimbursement based on prices reported to FDB or Medispan or Red Book. (Paul Ex. 12 (11/6/02 Robert Mozak Dep.), at 492:7-13; Paul Ex. 13 (10/30/01 Charles Rice Dep.), at 119:11-120:7; Paul Ex. 10 (5/15/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 296:6-22.)

15. From 1992 to April 2003 First DataBank published AWPs for Dey's drugs as reported by Dey. For over ten years the only AWPs listed in First DataBank's databases for Dey's NDCs were those submitted by Dey. (Paul Ex. 11 (Compl. for Injunctive Relief, *Dey v. First Data Bank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 8:22-28; Paul Ex. 14 (7/10/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 467:19-22.)

C. Dey Was Aware of the Prices Providers Paid For Its Products.

16. Dey maintained a computer database specifically for Medicaid AMP calculations that contained average prices for all Dey's drug products. (Paul Ex. 15 (5/14/08 Rule 30(b)(6) (Gary Walker) Dep.), at 151:10-21.)

17. Dey calculated the average sales prices for its drug products at least every month. (Paul Ex. 16 (7/9/08 Rule 30(b)(6) (Gary Walker) Dep.), at 376:6-11.)

18. Dey generated a monthly Sales Commentary that included monthly net sales by product, monthly average price by product per carton and per unit, and monthly net sales reports after rebates, discounts and administrative fees. (Paul Ex. 8 (11/7/02 Charles A. Rice Dep.), at Ex. 349.) Dey also generated monthly product summary reports that reflected wholesale cost, contract cost and chargeback difference per product. (Paul Ex. 17 (3/29/06 Lewis Mow Dep.), at Ex. 287.)

19. Dey sent its AWPs to First DataBank, but did not send the contract prices. (Paul Ex. 18 (1/20/03 Eve Gmeiner Dep.), at 99:12-100:5.)

D. Dey's Knowledge of Medicaid and Medi-Cal Policies

20. Dey was aware of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at 109:6-112:9, Exs. 231 and 880 (containing Medi-Cal's reimbursement rates for Dey's products).)

21. At various times during the relevant time period, Dey collected information concerning the particular reimbursement methodologies of the state Medicaid programs. (Paul Ex. 19 (2/10/03 Robert Ellis Dep.), at 12-17; Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at 109:6-112:9, Exs. 231 and 880; Paul Ex. 21 (12/28/02 First Databank Medicaid Coverage Report), at DL 59035, DL 59049, DL 59060-64, DL 59067-69; Paul Ex. 22 (12/17/98 FDB fax), at DL-CA 0063.)

22. Dey was aware that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWPs of the products. (Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at Ex. 231.)

E. Claims Submitted For All of Dey's Subject Drugs Were Materially False

23. Plaintiffs' expert, Dr. Leitzinger, used data provided by Dey to estimate the average prices paid by pharmaceutical wholesalers' customers [i.e., providers] for each of the 28 relevant Dey NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Dey for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each NDC. Paul Ex. 23 (Leitzinger Decl.), at ¶ 4. His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 23 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

24. Ex. 4 to Dr. Leitzinger's Report shows in column (6) the "spread" (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 28 relevant Dey NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 5.)

25. For over 94 percent of the Dey NDC/quarter combinations for which he had complete data, the AWP reported by Dey exceeded the average net quarterly prices paid by wholesalers' customers by at least 100 percent. For 62 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 800 percent. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 6.)

26. For purposes of calculating the overpayments made by the State for the 28 relevant Dey NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Dey by at least 25 percent. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25 percent above the average net price paid by wholesalers to Dey. That difference was the overpayment he found. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 7.)

F. Dey Acted Knowingly in Making the Above False Statements.

27. All of the information used by Dr. Leitzinger in computing actual average wholesale prices for the Subject Drugs was contained in Dey's business records.

28. Dey directly negotiated prices for its products with contract customers, even when a product was shipped through a wholesaler. For those customers, Dey knew at least the approximate price that the customers actually paid for the products. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084-PBS Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶¶ 52-53.)

29. The information Dey received from First DataBank regarding the setting of generic AWPs was that in order to receive generic listing by FDB the generic AWP had to be priced *at least* 10% below the corresponding brand AWP, but there was no information that the generic AWP should be set at that level when its average wholesale price was lower. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084-PBS, Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶ 68.)

30. Rather than setting and reporting AWPs that reflected prices generally and currently paid by providers for its drugs, Dey reported AWPs for generics at approximately 10% off the brand AWP and generally left that price unchanged. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084-PBS Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶¶ 66, 70.)

Dated: November 24, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on November 24, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
NICHOLAS N. PAUL